

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of

ECUMED HEALTH GROUP

FDA Docket: 2004H-0322

a corporation,

and

AMADOR REYES, JUAN C. CARRAI,  
RICHARD W. STONE, M.D., and  
ERLINDA E. ENRIQUEZ, M.D.,  
Individuals.

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**ANSWER TO ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY  
ON BEHALF OF RICHARD W. STONE, M.D.**

COMES NOW Richard Stone, M.D., and files this his Answer to the  
Administrative Complaint for Civil Money Penalty.

1. I Admit the applicability of the statute.
2. I do not contest the subject matter jurisdiction.
3. This is true to the best of my knowledge.
4. This is true to the best of my knowledge.
5. This is true to the best of my knowledge.
6. I believe I was the lead interpreting physician at EHG from October 30, 2000 through at least, January 31, 2002. I was not then, nor am I now aware, that I was responsible for insuring adequate clinical image quality at EHG. I am not aware now nor

was I then, that I was responsible for maintaining EHG certification under the MQSA.

7. Unknown.
8. Admit.
9. Admit.
10. I do not contest the statement of the law but I was never aware that the certified facilities certificate had expired.
11. I do not dispute this.
12. I do not dispute this.
13. I do not dispute the allegation but I never personally saw the certificate.
14. I am without knowledge. I do not dispute the allegation but I was not involved in the application process and was not aware of the facts as alleged.
15. I am without knowledge. I do not dispute the allegation but I was not involved in the application process and was not aware of the facts as alleged.
16. I do not dispute that the letter was addressed to Dr. Stone, dated September 14, 2001, but I do deny that I ever received the letter or was made aware by EHG of its contents.
17. I do not deny that ACR received testing data on October 2, 2001, but I deny that I knowingly submitted testing results in an attempt to complete the requirements of certification.

18. I do not dispute that the letter was addressed to Dr. Stone, dated November 1,, 2001, but I do deny that I ever received the letter or was made aware by EHG of its contents.
19. I do not dispute that the letter was addressed to Dr. Stone, dated November 14, 2001, but I do deny that I ever received the letter or was made aware by EHG of its contents.
20. I do not deny the allegations of Number 20 but I was not aware that occurred.
21. I am not aware of facts as stated in this paragraph.
22. I do not dispute that the letter is addressed to Dr. Stone, dated January 4, 2002, but I do deny that I ever received the letter or was made aware by EHG of its contents.
23. I am not aware of these facts. I was no longer associated with EHG at the time.
24. I am not aware of these facts. I was no longer associated with EHG at the time.
25. I am not aware of these facts. I was no longer associated with EHG at the time.
26. I am not aware of these facts. I was no longer associated with EHG at the time.
27. I am not aware of these facts. I was no longer associated with EHG at the time.
28. I was never personally aware of this.

29. Between December 9, 2001 and January 31, 2002, I admit that I interpreted mammography examinations performed at EHG but at the time I did not know that EHG did not have a certificate in violation of 42 U.S.C. § 263b (b) (1).
30. I deny that any of the letters FDA and ACR sent to respondents were ever personally received or reviewed by me.
31. I deny that I ever saw the certificate. I was not aware of any expiration date.
32. I understand that Petitioner seeks to assess civil money penalties against each Respondent.

### **DEFENSES**

I can assure the reviewing board that I, at no time, was aware that EHG did not hold proper certificates. I was also not aware that I was in any way responsible for maintaining the EHG certification under MQSA. At no time during my association with EHG, did I have an ownership or administrative position. I was hired by EHG on an independent contractor basis to review mammography films. I believe the films were all accurately interpreted and in my opinion, the clinical image quality of the mammograms I read was good.

I never had an office on the premises at 687 East 9<sup>th</sup> Street, Hialeah, FL 33010, I never spent much time at that location, and I never to my knowledge received any mail at that location. If in fact notices were sent to me addressed to that location, they were never passed on to me and no one at EHG ever advised

me that they had problems with their certification process or that they did not possess all proper certification as required by law.

I never intended to break the law. I understand that certain violations do not require intent, but nonetheless, I think that should be taken into consideration in reducing the penalty and assessment requested by this Complaint. Also, I am no longer working for EHG and I have a clean record with the Board of Medicine.

#### REQUEST FOR HEARING

I request a hearing in accordance with the procedures established in FDA's regulations governing civil money penalty proceedings

I HEREBY CERTIFY that a true and correct copy of the foregoing was mailed to: Michael N. Varrone, United State Food and Drug Administration, 5600 Fishers Lane (GCF-1), Rockville, MD 20857.



Richard W. Stone, M.D.  
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~~Miami, FL 33179~~  
305-945-1580

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# 102

NMB FL 33162